

### **REMARKS/ARGUMENTS**

Claims 1-28 are pending in this application.

In the Office Action of May 19, 2004, the Examiner has maintained the rejection of Claims 1-28 of the above-referenced application for double patenting over Claims 1-28 of U.S. Patent No. 5,164,796 (the "796 Patent"). Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner maintains that the pending claims are not patentably distinct from the claims of the 796 Patent because "both inventions use semi-permeable membranes or compositions." The Examiner further asserts that the filter means of the present invention are operational in the invention claimed in the 796 Patent and thus, there is substantial overlap of the subject matter claimed in both inventions.

Applicants respectfully reassert that the present claims are patentably distinct from the claims of the 796 Patent. First, the claims of the 796 Patent do not disclose, teach or suggest a container having an inlet and an outlet as required by the present invention. The claims of the 796 Patent require the presence of a sealable, sterilizable container. See the 796 Patent at column 10, lines 7-39. The container is further provided in the specification of the 796 Patent as being a sealed container. See the 796 Patent at column 2, lines 36-39 and column 3, lines 48-49. The container does not have any inlets or outlets for the specimen to flow into and out of the container, rather, the specimen is housed in the container for incubation. See the 796 Patent at column 3, lines 46-49. The present invention, though, requires a container defining a chamber therein and having an inlet and an outlet in fluid

communication with the chamber. See the present application at page 2, lines 9-11. A specimen is passed into the chamber through the inlet and out of the chamber through the outlet. See the present application at page 2, lines 14-16. The specimen is not housed nor cultured in the container.

Second, the filter means of the present invention are not operational in the invention claimed in the 796 Patent. It is an object of the 796 Patent to monitor pH or CO<sub>2</sub> changes in a specimen within a sealed container without entering the container during the monitoring process. See the 796 Patent at column 2, lines 36-39. Further, the claims of the 796 Patent require the specimen to be cultured in a culture medium and this medium enhances the production of certain microbial metabolic products. The monitoring process or incubation period for the specimen with the medium may last up to seven days before the population of organisms reaches a critical level or an increase in metabolic products can be measured. See the 796 Patent at column 4, lines 3-8.

The filter means of the present invention is mounted in the container between an inlet and an outlet and the filter means collects the microorganisms as a specimen is passed into the inlet, through the filter means and out of the container through the outlet. If the filter means of the present invention were added to the container of the 796 Patent, a specimen could not be cultured in the sterile culture medium as required in the claims of the 796 Patent as the microorganisms in the specimen would be caught by the filter when the specimen is added to the container and the specimen would be passed out of the container through the outlet. As such, the instrument in the 796 Patent would not be operational as claimed if the filter means of the present invention were added to the instrument of the 796

Patent. Therefore, it would not have been an obvious modification to add the filter means of the present invention to the instrument of the 796 Patent.

Accordingly, Applicants respectfully submit that the present Claims 1-28 are patentably distinct from the claims of the 796 Patent and this rejection should be withdrawn.

Also in the Office Action, the Examiner has maintained the rejection of Claims 1-21 of the above-referenced application for double patenting over Claims 1-21 of U.S. Patent No. 5,094,955 (the "955 Patent"). Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner maintains that Claims 1-21 are not patentably distinct from Claims 1-21 of the 955 Patent because "both inventions use semi-permeable membranes or compositions." The Examiner further asserts that the filter means of the present invention are operational in the invention claimed in the 955 Patent and thus, there is substantial overlap of the subject matter claimed in both inventions.

Applicants respectfully reassert that the present Claims 1-21 are patentably distinct from the claims of the 955 Patent. First, the claims of the 955 Patent do not disclose, teach or suggest a container having an inlet and an outlet as required by the present invention. The claims of the 955 Patent require the presence of a sealable specimen container in which the integrity of the container is not violated after sealing. See the 955 Patent at column 17, lines 30-45. The container is further provided in the specification of the 955 Patent as being a sealed container. See the 955 Patent at column 1, lines 10-14 and column 2, lines 31-36. The container does not have any inlets or outlets for the specimen to flow into and out of the

container, rather, the specimen is housed and cultured in the container. See the 955 Patent at column 2, lines 31-36. The present invention, though, requires a container defining a chamber therein and having an inlet and an outlet in fluid communication with the chamber. See the present application at page 2, lines 9-11. A specimen is passed into the chamber through the inlet and out of the chamber through the outlet. See the present application at page 2, lines 14-16. The specimen is not housed nor cultured in the container.

Second, the filter means of the present invention are not operational in the invention claimed in the 955 Patent. The 955 Patent provides for monitoring pH or CO<sub>2</sub> changes in a specimen using a growth medium and a sealed container without entering the container after the sample is prepared and the container is sealed. See the 955 Patent at column 1, lines 10-14. Further, the claims of the 955 Patent require the specimen to be cultured in a culture medium and this medium enhances the production of certain microbial metabolic products. The monitoring process or incubation period for the specimen with the medium may last up to seven days before the population of organisms reaches a critical level or an increase in metabolic products can be measured. See the 955 Patent at column 4, lines 56-61.

The filter means of the present invention is mounted in the container between an inlet and an outlet and the filter means collects the microorganisms as a specimen is passed into the inlet, through the filter means and out of the container through the outlet. If the filter means of the present invention were added to the container of the 955 Patent, a specimen could not be cultured with the culture medium as required in the claims of the 955 Patent as the microorganisms in the specimen would be caught by the filter when the specimen is added to the container and the specimen would be passed out of the container

through the outlet. As such, the instrument in the 955 Patent would not be operational as claimed if the filter means of the present invention were added to the instrument of the 955 Patent. Therefore, it would not have been an obvious modification to add the filter means of the present invention to the instrument of the 955 Patent.

Therefore, the present Claims 1-21 are patentably distinct from the claims of the 955 Patent and this rejection should be withdrawn.

In addition, the Examiner has maintained the rejection of Claims 22-28 for double patenting over Claims 1-21 of U.S. Patent No. 5,217,876 (the "876 Patent"). Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner maintains that Claims 22-28 are not patentably distinct from Claims 1-9 of the 876 Patent because "both inventions use semi-permeable membranes or compositions." The Examiner further asserts that the filter means of the present invention are operational in the invention claimed in the 876 Patent and thus, there is substantial overlap of the subject matter claimed in both inventions.

Applicants respectfully reassert that the present Claims 22-28 are patentably distinct from the claims of the 876 Patent. First, the claims of the 876 Patent do not disclose, teach or suggest the use of a container having an inlet and an outlet as required by Claims 22-28 of the present invention. The claims of the 876 Patent require the use of a sterile, specimen container. See the 876 Patent at column 8, lines 45-55. The container is further provided in the specification of the 876 Patent as being a sealed container. See the 876 Patent at column 1, lines 10-15 and column 2, lines 32-36. The container does not have any inlets or

outlets for the specimen to flow into and out of the container, rather, the specimen is housed and cultured in the container. See the 876 Patent at column 2, lines 32-36. The present invention, though, requires the use of a container defining a chamber therein and having an inlet and an outlet in fluid communication with the chamber. See the present application at page 2, lines 9-11. A specimen is passed into the chamber through the inlet and out of the chamber through the outlet. See the present application at page 2, lines 14-16. The specimen is not housed nor cultured in the container.

Second, the filter means of the present invention are not operational in the invention claimed in the 876 Patent. The 876 Patent provides for monitoring pH or CO<sub>2</sub> changes in a specimen using a growth medium and a sealed container without entering the container after the sample is prepared and the container is sealed. See the 876 Patent at column 1, lines 11-15. Further, the claims of the 876 Patent require the specimen to be incubated with a growth medium and this medium enhances the production of certain microbial metabolic products. The monitoring process or incubation period for the specimen with the medium may last up to seven days before the population of organisms reaches a critical level or an increase in metabolic products can be measured. See the 876 Patent at column 3, line 66 through column 4, line 2.

The filter means of the present invention is mounted in the container between an inlet and an outlet and the filter means collects the microorganisms as a specimen is passed into the inlet, through the filter means and out of the container through the outlet. If the filter means of the present invention were added to the container used in the methods of the 876 Patent, a specimen could not be incubated in the growth medium as required in the claims of the 876 Patent as the microorganisms in the specimen would be caught by the filter

when the specimen is added to the container and the specimen would be passed out of the container through the outlet. As such, the methods of the 876 Patent would not be operational as claimed if the filter means of the present invention were added to the container used in the methods of the 876 Patent. Therefore, it would not have been an obvious modification to add the filter means of the present invention to the container of the method claims of the 876 Patent.

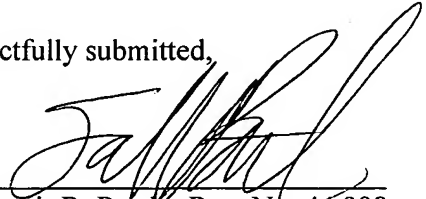
Accordingly, Applicants respectfully submit that the present Claims 22-28 are patentably distinct from the claims of the 876 Patent and this rejection should be withdrawn.

In view of the foregoing, it is respectfully submitted that the claims are in condition for allowance and prompt notice to that effect is earnestly solicited.

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Respectfully submitted,

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